



Iowa Board of Pharmacy June 23, 2020 Minutes

Members Present

Jason Hansel, Chair
Brett Barker, Vice-Chair
Gayle Mayer
Ed McKenna
Dane Nealson
Joan Skogstrom
Kathy Stone
Sherill Whisenand

Mitch Barnett, Associate Director of PMP
Laura Steffensmeier, Assistant Attorney General
Amanda Woltz, Administrative Assistant

Compliance Officers

Christie Carlson
Curt Gerhold
Mark Mather
Sue Mears
Jean Rhodes
Dan Sedlacek
Jennifer Tiffany
Jim Wolfe

Staff Present

Andrew Funk, Executive Director
Therese Witkowski, Executive Officer

Call to Order & Announcements

At 9:00 a.m., on Tuesday, June 23, 2020, Jason Hansel, Chair, called the meeting of the Iowa Board of Pharmacy to order.

Public Comment Period

None

Approval of Minutes

1. May 5, 2020 Open Session Minutes

Motion by Brett Barker, second by Gayle Mayer, to approve the Open Session Minutes of the May 5, 2020, meeting as presented. Motion approved unanimously.

Requests

1. Requests to extend existing waiver of 657 IAC 17.3(1)“c” requiring evidence of current VAWD accreditation by the NABP
 - a. Northwind Pharmaceuticals, License No. 5698, Indianapolis, IN

Motion by Brett Barker, second by Gayle Mayer, to approve the waiver request to December 31, 2020. Motion approved unanimously.

- b. HUB Pharmaceuticals, License No. 8207, Plymouth, MI

Motion by Brett Barker, second by Gayle Mayer, to approve the waiver request provided the facility obtains NCDQS accreditation within 60 days. The waiver authorizes the facility to renew its 2020 wholesale distributor license at this time while it continues to finalize NCDQS accreditation.

Petitions for Exemption from Mandate for Electronic Transmission of Prescriptions

1. Iowa Digestive Disease Center

Motion by Gayle Mayer, second by Ed McKenna, to approve the request for extension to December 31, 2020. Motion approved unanimously.

Licensure/Registration Applications

1. Patrick Chau, CSAR Applicant, Sioux City

Motion by Sherill Whisenand, second by Dane Nealson, to approve the Registration by Consent Agreement. Motion approved unanimously.

2. Jacob Alanis, Pharmacist-intern Applicant, Mount Pleasant

Motion by Dane Nealson, second by Sherill Whisenand, to deny the pharmacist-intern registration application. Motion passed unanimously.

Reports & Informational Items

1. Executive Director's Report

Board Member Appointment

The Senate confirmed all Board members Brett Barker, Gayle Mayer, and Sherill Whisenand's appointments.

Staffing

The Board is creating a new position for a pharmacy technician that will primarily be tasked with assisting Board staff with the naloxone distribution program and PMP Field Audit Quality Initiative and Training Project (FAQ-TIP). Staff is currently finalizing the candidate selection process.

Director Clabaugh announced his retirement, effective July 31, 2020.

Licensing

Pharmacist renewal period ends June 30, 2020. There are 6549 pharmacists licensed with the Board. Licenses are renewed every two years, 3254 licensees renew on even years. So far, 2645 licensees have renewed in 2020.

2. Meetings and Travel

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|--------------------------------------|-------------------|
| • Iowa Pharmacy Stakeholder call | July 14 10am-12pm |
| • PMP Advisory Council Meeting | July 17 1pm-2pm |
| • Rules Committee Meeting | July 21 |
| • NABP District V Meeting (Virtual)* | August 7 |
| • Next BOP Meeting | August 25-26 |

*District V meeting will take place in Winnipeg, Manitoba in August, 2021

All upcoming meetings will be held via telecommunications.

3. Naloxone Distribution Program

The Naloxone Distribution program is a new program that will allow persons in a position to assist to access Narcan 4mg from pharmacies at no cost. The program is funded by federal grants to IDPH.

4. Nicotine Replacement Therapy Program

The IDPH Division of Tobacco Use Prevention and Control is interested in initiating a similar program (as above) that would allow pharmacies to electronically bill the State for nicotine replacement therapy. Conversations surrounding this project are just starting to unfold.

5. PMP

Mitch Barnett provided a program update.

6. Medication Disposal Report

Jen Tiffany provided a program update.

7. IMP3 Report

Amanda Woltz provided a program update.

8. 50 Year Pharmacists

Informational Item

9. FDA Memorandum of Understanding (MOU)

Jean Rhodes provided a summary of the final version of the MOU.

Rules and Legislation

1. Update on current legislation

- a. Senate File 2119 - Board of Pharmacy Controlled Substances Bill (Signed by Governor Reynolds June 1, 2020; Effective June 1, 2020)
- b. Senate File 2120 - Board of Pharmacy PMP Bill (Signed by Governor Reynolds June 1, 2020; Effective July 1, 2020)
- c. Senate File 2357 - Physician Assistant Bill (Signed by Governor Reynolds March 18, 2020; Effective March 18, 2020)
- d. House File 2389 - Administrative Rules Review Committee Code clean up (Enrolled - not yet signed by Governor Reynolds; When signed, effective July 1, 2020)
- e. House File 2627 - Professional Licensing Reform Bill (Not yet enrolled; When signed, Division I effective January 1, 2021, Division II effective upon enactment)

2. Update on current rulemakings

Sue Mears provided an updated on current rulemakings.

1. Legislative Update

- 2. Proposed for Adoption and Filing to amend Chapter 10, "Controlled Substances" (ARC 4837C)

The amendment clarifies the board's expectation that an individual controlled substances act registrant cancels their registration when the registration is no longer needed (such as when discontinuing practice in Iowa) and, when having done so, is allowed to later renew when the registrant returns to practice in Iowa or wishes to again engage in activities which require a registration for the standard renewal fee.

Motion by Brett Barker, second by Dane Nealson, to adopt. Motion passed unanimously.

- 3. Proposed for Notice of Intended Action to amend Chapter 1, "Purpose and Organization," Chapter 2, "Pharmacist Licenses," Chapter 8, "Universal Practice Standards," Chapter 10, "Controlled Substances," Chapter 13, "Telepharmacy Practice," Chapter 16, "Nuclear Pharmacy Practice," Chapter 26, "Petitions for Rule Making," Chapter 34, "Rules for Waivers and Variances," and Chapter 39, "Expanded Practice Standards," to implement Code changes from 2019 and 2020 legislative sessions

The proposed amendments bring 657 Iowa Administrative Code in alignment with Code changes made during the 2019 and 2020 legislative sessions. The subjects of the Code changes include:

- Oversight of the board's executive director (2019 House File 766),
- Service animals or service-animals-in-training (2019 Senate File 341),
- Extension of future repeal date for physician-signed immunization protocols (2020 House File 2627),
- Prescriptions issued by physician assistants (2020 Senate File 2357),
- Waivers and variances (2020 House File 2389), and
- Submission of the disposition of a petition for rulemaking to the administrative rules review committee (2020 House File 2389).

Motion by Brett Barker, second by Dane Nealson, to file for Notice of Intended Action. Motion passed unanimously.

4. Proposed for Notice of Intended Action to amend Chapter 2, "Pharmacist Licenses," to remove the requirement that a license transfer applicant's original license by examination be the license upon which the transfer is based

The proposed amendment would remove the requirement that a pharmacist's original license issued by examination be current and active at the time of license transfer and allow the pharmacist to license transfer from any state in which the pharmacist holds a current and active license to practice pharmacy. Since 2004, every state in the United States has required successful completion of the same competency exam for initial licensure (since 1986 for all states but California) and, to date, 40 states have removed the requirement that license transfer can only occur from the original license by examination.

Motion by Brett Barker, second by Gayle Mayer, to file for Notice of Intended Action. Motion passed unanimously.

5. Proposed for Notice of Intended Action to amend Chapter 4, "Pharmacist-Interns," to provide consistency and conduct an overall 5 year review

Pursuant to Iowa Code 17A.7(2), the board conducted a five-year review of this chapter of rules. This proposed rulemaking:

- Provides consistency in the experiential training of pharmacist-intern graduates in the United States and of foreign pharmacy programs,
- Provides consistent language with other board rules relating to the use of an ITIN number in lieu of a social security number,
- Simplifies the subrule relating to delegated functions of a pharmacist-intern,

- Removes the reference to a license surcharge for the board's monitoring program which the board no longer assesses,
- Allows the board to require the submission of a \$15 fee for verification of a pharmacist-intern registration or certification of hours,
- Provides language relating to the required notice to the board following criminal or disciplinary action, and
- Rearranges rules for clarity.

Motion by Brett Barker, second by Dane Nealson, to file for Notice of Intended Action. Motion passed unanimously.

6. Proposed for Notice of Intended Action to amend Chapter 10, "Controlled Substances," to incorporate language relating to DEA Form 222 single sheet and clarify the expectation for perpetual inventory records

The proposed rulemaking clarifies the expectation that a registrant's perpetual inventory must at all times accurately reflect the actual on-hand inventory of the substance(s) as well as simplifies the rule relating to the purchase of schedules I or II controlled substances. Federal regulations were recently amended to now allow a single page order form for the purchase of schedule I and II substances, but continues to allow the use of the prior triplicate order form for a period of time in addition to the electronic ordering process.

Motion by Brett Barker, second by Dane Nealson, to file for Notice of Intended Action. Motion passed unanimously.

7. Proposed for Notice of Intended Action to amend Chapter 10, "Controlled Substances," and Chapter 12, "Precursor Substances," to temporarily schedule five substances, remove the substances which have now been permanently scheduled, and incorporate language from Senate File 2119

The proposed amendments:

- Temporary place into the Iowa Controlled Substances Act five substances (one fentanyl precursor into schedule II, an FDA-approved treatment for insomnia into schedule IV, an FDA-approved treatment for seizures into schedule V, and two chemicals used in the manufacture of illicit fentanyl as precursor substances),
- Remove the names of prior substances temporarily scheduled by rule as a result of the substances being permanently scheduled via the passage of Senate File 2119 during the legislative session,
- Amend subrule 10.38(3) to incorporate updated language in Senate File 2119, and
- Rescind 10.30(2), paragraph "g", in response to Section 1 in Senate File 2357 which removes the requirement that the name of a supervising physician is required to be included on a prescription issued by a physician assistant.

Motion by Brett Barker, second by Dane Nealson, to file for Notice of Intended Action. Motion passed unanimously.

8. Proposed for Notice of Intended Action to amend Chapter 17, "Wholesale Distributor Licenses," and Chapter 43, "Third-Party Logistics Provider Licenses," to allow alternate NCDQS accreditation for initial licensure and update the name of the NABP accreditation program

These proposed amendments would allow wholesale distributors and third-party logistics providers (3PL) which are seeking initial licensure in Iowa to attain Quality and Security (QAS) accreditation through National Coalition for Drug Quality and Security (NCDQS) in lieu of accreditation through National Associations of Boards of Pharmacy (NABP), but requires accreditation through NABP by the licensee's second renewal. Following passage of the federal Drug Quality and Security Act, including the Drug Supply Chain Security Act, in November 2013, the Board implemented a requirement that entities involved in the drug supply chain must be accredited as a requirement for licensure in Iowa. At the time of implementation of the requirement, NABP's accreditation program (Verified Accredited Wholesale Distributors or "VAWD") was the only accreditation program in the marketplace. A second program is now available and has been authorized by the Board in a number of waiver petitions as an initial accreditation to meet the minimum standard until VAWD accreditation can be attained. Due to the limited time since initiation of the QAS program and the reported length of time to attain accreditation through NABP, the board is proposing to allow QAS accreditation in lieu of NABP's accreditation to initiate licensure in Iowa and continue to require NABP's accreditation for the licensee's second renewal. Additionally, NABP has renamed its accreditation program to "NABP Drug Distributor Accreditation."

Motion by Brett Barker, second by Sherill Whisenand, to file for Notice of Intended Action. Motion passed unanimously.

9. Proposed for Notice of Intended Action to amend Chapter 21, "Electronic Data and Automated Systems in Pharmacy Practice," to require a prescription transmitted electronically to include the phone number at which the prescriber may be contacted for timely consultation about patient care matters

The proposed amendments provide that an electronically transmitted prescription must include the telephone number where the practitioner can be contacted and updates a reference.

Motion by Gayle Mayer, second by Ed McKenna, to file for Notice of Intended Action. Motion passed unanimously.

Closed Session

Brett Barker moved at 10:55 a.m. to move to closed session with Dane Nealson seconding it. The motion was approved by roll call vote.

Returned to open session at 2:56 p.m.

1. Closed Session Minutes

Motion by Brett Barker, second by Dane Nealson to approve the Closed Session Minutes of the May 5, 2020, meeting as presented. Motion approved unanimously.

2. Close With No Further Action

Motion by Brett Barker, second by Dane Nealson, to close with no further action the following investigative files in complaint numbers: 2020-0054, 2020-0058, 2020-0007, 2018-0117, 2020-0008, 2020-0043, 2020-0050, 2020-0052, and 2020-0064. Motion approved unanimously.

3. Close With No Further Action

Motion by Joan Skogstrom, second by Gayle Mayer, to close with no further action the following investigative file: 2020-0036. Motion passed unanimously with Ed McKenna abstaining.

4. Administrative Warning

Motion by Brett Barker, second by Gayle Mayer, to issue an administrative warning to the pharmacy in 2020-0029, the pharmacy, pharmacist, and pharmacist-intern in 2020-0047 and the pharmacy in 2020-0048. Motion approved unanimously.

5. Administrative Warning

Motion by Gayle Mayer, second by Dane Nealson, to issue an administrative warning to the technician in 2020-0040. Motion passed unanimously with Brett Barker abstaining.

6. Letter of Education

Motion by Brett Barker, second by Gayle Mayer, to issue a letter of education to the pharmacy and PIC in 2020-0003, the pharmacy and pharmacist in 2020-0028, the pharmacy and PIC in 2020-0033, the technician in 2020-0037, the pharmacist in 2020-0071, and the pharmacy and PIC in 2020-0031. Motion approved unanimously.

7. Letter of Education

Motion by Joan Skogstrom, second by Sherill Whisenand, to issue a letter of education to the pharmacist in 2020-0051. Brett Barker, Jason Hansel, Kathy Stone, Joan Skogstrom, and Sherill Whisenand in favor. Dane Nealson, Ed McKenna, Gayle Mayer opposed. Motion passed.

8. Close With No Further Action

Motion by Ed McKenna, second by Brett Barker, to close with no further action the following investigative files: 2020-0018, 2020-0019, 2020-0010, 2020-0011, 2020-0013, 2020-0014, and 2020-0017. Motion passed unanimously.

9. Voluntary Surrender

Motion by Brett Barker, second by Sherill Whisenand, to approve the Voluntary Surrender in the following case. Motion approved unanimously.

- A. 2019-0129 Steven Beevers, DPM, CSA Registration 1710073

10. Combined Statement of Charges, Settlement Agreement, and Final Order

Motion by Sherill Whisenand, second by Gayle Mayer, to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in the following cases. Motion approved unanimously.

- A. 2019-0217 Price Chopper, License 1527, Des Moines
- B. 2020-0001 Hy-Vee Pharmacy 1235 License 1201, Grinnell
- C. 2020-0030 Courtney Martin, CphT Registration 18649, Van Horne
- D. 2020-0044 Anthony Pape, RPh, License 22557, Dubuque
- E. 2019-0127 Walgreens 05886, License 1150, Keokuk

Adjournment



Amanda Woltz, Administrative Assistant and Recording Secretary



Andrew Funk
Executive Director



Jason Hansel
Board Chair

APPROVED THIS 26th DAY OF August, 2020